SONOTECH® INC
Sonotech, Inc.
774 Marine Dr. Bellingham, WA 98225
360-671-9122 fax 360-671-9024

510(k) Application: **Endo-Glide Lubricant**

Registration # 2523891

2-4-02

K013701

510(k) Summary

Date Prepared: _____

SONOTECH, INC.
774 Marine Drive
Bellingham, WA 98225
Contact Person: Margaret J. Larson
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Device Name

Proprietary name: **Endo-Glide™**

Common name: lubricant

Classification name: endoscopic, transurethral and surgical instrumentation lubricant

Statement of substantial equivalence

Endo-Glide is equivalent in formula to:

A. VivoSonic In Vivo Biocompatible/Biodegradable Sterile Ultrasound Couplant; (Sonotech, Inc.) K984562, clearance received June 8, 1999; MUI; Class II

Endo-Glide is equivalent in use to:

A. K-Y Jelly; for transurethral surgical instruments (Johnson & Johnson Professionals, Inc.) K780386, clearance received 04/13/1978; FHX78, Class II
B. K-Y Jelly; patient lubricant (Johnson & Johnson Professionals, Inc.) K810310, clearance received 04/21/1981; KMJ, Class I
C. Surgilube

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Device Description

Endo-Glide™ is a lubricant that is biocompatible with all hollow viscera, is in vivo biocompatible with tissue and body fluids, is in vivo biodegradable and is recognized as safe for oral administration[1]. **Endo-Glide** is an excellent film former, requiring a thin coating to adequately lubricate an instrument, thus using less material. A thin film of **Endo-Glide** has excellent adherence and will not "snowplow" when inserted into an orifice, which can create dry spots on an instrument, and most particularly on an endoscope. **Endo-Glide** will be offered in sterile and non-sterile packaging for endoscopic, transurethral and surgical instrumentation lubrication.

Intended Use

Endo-Glide will be used to lubricate the insertion and passage of imaging devices such as endoscopes, ultrasound transducers, and transesophageal echocardiography transducers, catheters and surgical instrumentation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2002

Ms. Margaret J. Larson
President
Sonotech, Inc.
774 Marine Drive
Bellingham, Washington 98225

Re: K013701
Trade/Device Name: Endo-Glide Lubricant
Regulation Number: 892.1570, 876.1500
Regulation Name: Diagnostic ultrasonic transducer, endoscope and accessories
Regulatory Class: II
Product Code: ITX, GCJ
Dated: November 5, 2001
Received: November 8, 2001

Dear Ms. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013701

Device Name: ENDO-GLIDE LUBRICANT

Indications For Use:

Lubricate the insertion and passage of imaging devices and surgical instrumentation, such as endoscopes, ultrasound transducers, transesophageal echocardiography (TEE) transducers, catheters and surgical instrumentation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013701